

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TAKEDA PHARMACEUTICALS U.S.A., INC.,

Plaintiff,

v.

WEST-WARD PHARMACEUTICAL
CORPORATION, HIKMA AMERICAS, INC., and
HIKMA PHARMACEUTICALS PLC,

Defendants.

Civil Action No. 14-cv-1268

REDACTED VERSION D.I. 9

**DECLARATION OF MARY W. BOURKE IN SUPPORT OF
PLAINTIFF TAKEDA PHARMACEUTICALS U.S.A., INC.'S MOTION FOR A
TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

I, Mary W. Bourke, do hereby declare:

1. I am an attorney with the law firm of Womble Carlyle Sandridge & Rice, LLP, counsel for Plaintiff Takeda Pharmaceuticals U.S.A., Inc. in the above-captioned matter.
2. I submit this Declaration in Support of Plaintiff Takeda Pharmaceuticals U.S.A., Inc.'s ("Takeda") Motion for a Temporary Restraining Order and Preliminary Injunction.
3. Attached as Exhibit A is a true and correct copy of the NDA approval letter for MitigareTM (colchicine) capsules, 0.6 mg, for NDA No. 204820, dated September 26, 2014.
4. Attached as Exhibit B is a true and correct copy of the FDA approved prescribing information for MitigareTM, as posted on the U.S. Food and Drug Administration's ("FDA") website, and as revised in September 2014.
5. Attached as Exhibit C is a true and correct copy of U.S. Patent Number 7,981,938, entitled COLCHICINE COMPOSITIONS AND METHODS, issued July 19, 2011.
6. Attached as Exhibit D is a true and correct copy of U.S. Patent Number 8,097,655, entitled METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND MACROLIDE ANTIBIOTICS, issued January 17, 2012.

7. Attached as Exhibit E is a true and correct copy of the FDA approved prescribing information of Colcrys®, as revised in November 2012.

8. Attached as Exhibit F is a true and correct copy of the Declaration of Michael Raya dated March 2, 2011 and titled Docket No. FDA-2010-P-0614 – Comment to Citizen Petition on Single-Ingredient Colchicine Applications.

9. Attached as Exhibit G is a true and correct copy of the September 19, 2011 update to Guidance for FDA Staff and Industry Marketed Unapproved Drugs – Compliance Policy Guide, which is an update from the original June 2006 publication.

10. Attached as Exhibit H is a true and correct copy of the Citizen Petition filed by Mutual Pharmaceutical Company dated November 26, 2010.

11. Attached as Exhibit I is a true and correct copy of the complaint in *Mutual Pharmaceutical Company, Inc.; AR Scientific, Inc.; and AR Holding Company, Inc. v. West-Ward Pharmaceutical Corporation*, C.A. No. 11-2276 (MLC)(DEA), filed April 21, 2011 in the United States District Court for the District of New Jersey.

12. Attached as Exhibit J is a true and correct copy of the FDA response to Mutual Pharmaceutical Company's Citizen Petition, dated May 25, 2011.

13. Attached as Exhibit K is a true and correct copy of a press release from Hikma Pharmaceuticals PLC regarding sales of colchicine in the United States and the litigation between Hikma and Mutual, dated October 18, 2010.

14. Attached as Exhibit L is a true and correct copy of the Notice of Dismissal Without Prejudice filed in *Mutual Pharmaceutical Company, Inc.; AR Scientific, Inc.; and AR Holding Company, Inc. v. West-Ward Pharmaceutical Corporation*, C.A. No. 11-2276 (MLC)(DEA), on May 26, 2011 in the United States District Court for the District of New Jersey.

15. Attached as Exhibit M is a true and correct copy of a chart prepared by counsel for Takeda showing the elements of representative claims 3 and 5 of U.S. Patent Number 8,097,655.

16. Attached as Exhibit N is a true and correct copy of an FDA alert entitled “Information for Healthcare Professionals: New Safety Information for Colchicine (marketed as Colcrys)”, first published on July 30, 2009, as accessed at the FDA’s website (<http://www.fda.gov>) on October 5, 2014.

17. Attached as Exhibit O is a true and correct copy of a chart prepared by counsel for Takeda showing the elements of representative claims 5 and 6 of U.S. Patent Number 7,964,648.

18. Attached as Exhibit P is a true and correct copy of a chart prepared by counsel for Takeda showing the elements of representative claims 1 and 2 of U.S. Patent Number 8,440,722.

19. Attached as Exhibit Q is a true and correct copy of U.S. Patent Number 7,964,648, entitled METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT, issued on June 21, 2011.

20. Attached as Exhibit R is a true and correct copy of the FDA approved prescribing information for CALAN® verapamil hydrochloride tablets, as available from the FDA.

21. Attached as Exhibit S is a true and correct copy of a chart prepared by counsel for Takeda showing the elements of representative claim 1 of U.S. Patent Number 7,981,938 and representative claim 1 of U.S. Patent Number 7,964,647.

22. Attached as Exhibit T is a true and correct copy of the 2012 American College of Rheumatology Guideline for Management of Gout. Part 2: Therapy and Antiinflammatory Prophylaxis of Acute Gouty Arthritis, as published in 64 ARTHRITIS CARE & RESEARCH No. 10, pp. 1447-1461 (October 2012).

23. Attached as Exhibit U is a true and correct copy of U.S. Patent Number 8,440,722, entitled METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT, issued on May 14, 2013.

24. Attached as Exhibit V is a true and correct copy of U.S. Patent Number 7,964,647, entitled COLCHICINE COMPOSITIONS AND METHODS, issued June 21, 2011.

I declare under penalty of perjury that the foregoing is true and correct to the best of my information and belief.

This Declaration is executed this 6th day of October 2014.

/s/ Mary W. Bourke
Mary W. Bourke (#2356)